

Coronavirus Disease 2019 (COVID-19)



On February 11, 2020 the World Health Organization **announced** an official name for the disease that is causing the current outbreak of coronavirus disease, COVID-19. CDC will be updating our website and other CDC materials to reflect the updated name.

Information for Laboratories COVID-19 Requests for Diagnostic Panels and Virus

How do I order a reagent diagnostic panel?

The [International Reagent Resource \(IRR\)](#)  will distribute the diagnostic panel and most of the associated reagents.

Which labs will receive the diagnostic panel?

The Food and Drug Administration (FDA) authorized the Emergency Use Authorization (EUA) on February 4, 2020.

- CDC's diagnostic panel is intended for use by laboratories designated by CDC as qualified, and in the United States certified under the Clinical Laboratory Improvement Amendments (CLIA) to perform high complexity tests. This includes U.S. state and local public health laboratories and Department of Defense (DoD) laboratories. The test also will be shipped to qualified international laboratories, such as World Health Organization (WHO) Global Influenza Surveillance Response System (GISRS) laboratories For more information, see the section labeled [CDC Laboratory Test Kit Distribution \(general audiences\)](#).
- Each laboratory that places an order will receive one diagnostic panel initially, and each panel can test 700-800 patient specimens.

What other equipment will labs need to perform tests using the diagnostic panel?

The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel also requires the use of additional authorized materials and authorized ancillary reagents that are not included with the test but are commonly used in clinical laboratories and are described in the authorized CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Instructions for Use Package Insert.

The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel requires the following control materials, or other authorized control materials; all controls listed below must generate expected results for a test to be considered valid, as outlined in the CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel Instructions for Use:

- Human Specimen Control (HSC): A human cell culture preparation used as an extraction control and positive control for the RNase P primer and probe set that is extracted and tested concurrently with each specimen extraction run.
- Positive Control for COVID-19 (nCoVPC): Run with each batch of specimens. Monitors for failures of rRT-PCR reagents and reaction conditions.
- No Template Control (NTC): Nuclease-free water included in each run. Monitors for reagent and system contamination.

Should I be testing all patients for COVID-19?

At this time, CDC only recommends diagnostic testing of patients who meet the clinical criteria for a COVID-19 person under investigation (PUI), per [Interim Guidelines for Collecting, Handling and Testing Clinical Specimens from Persons Under Investigation \(PUIs\) for Coronavirus Disease 2019 \(COVID-19\)](#).

- At this time, PUIs are identified as individuals with a history of travel to China or close contact with a person confirmed to have the COVID-19 illness *and* symptoms of respiratory illness such as cough or shortness of breath.
- For more information about interpreting test results, see section labeled "Interpretation of test results from CDC 2019 novel coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel."

What safety equipment should labs use when using the diagnostic tool?

Use appropriate personal protective equipment when collecting and handling specimens from individuals suspected of being infected with COVID-19 as outlined in the CDC Interim Guidelines for Collecting, Handling and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19).

How can my lab get the virus?

The National Institute of Health (NIH)'s [Biodefense and Emerging Infections Research Resources Repository](#) (BEI Resources) will provide laboratories with COVID-19.

I believe that I have found a treatment or vaccine for COVID-19. Is CDC the best place to submit my idea

BARDA is providing a portal to support U.S. government medical countermeasure research and development. Interested stakeholders can learn more [here](#) .

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